

The **IREx Study Manager** is someone from the lead study team or coordinating center who uses IREx to oversee participating site readiness for single IRB (sIRB) review. For more detailed information on how to use IREx, check out the Study Manager Resources page <u>here</u>.

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## **Conversation with the Single IRB**

- A. **Discuss** the submission process with the sIRB.
  - Review the <u>IREx Single IRB Instructions Template</u> for relying sites
  - Process for managing consent form (e.g., whether a template is being used)
  - Process for capturing local considerations from sites (e.g., via IREx surveys, including if the study will request local considerations updates throughout the life of the study)
  - Process for submitting sites for review (e.g., as an amendment, as a site add)
- B. Clarify what roles you are responsible for in IREx as a Study Manger vs the sIRB. Who will:
  - Upload Initial Approval for the Overall Study/Lead Site & Publish Approval
  - Add or remove participating sites to the study
  - Request Required Agreements
  - Grant study access to participating HRPP and study teams
  - Export participating sites' reliance and local review documentation for submission to the sIRB
  - Upload Reviewing IRB Site Approvals
  - Manage study-wide amendments and continuing reviews

STEP	SUBMIT THE LEAD SITE TO THE SIRB			
1	<ul> <li>The sIRB will review the submission and create the study in IREx.</li> <li>You will receive access to IREx via an email notification after the study is created.</li> <li>While you wait for the sIRB to approve the Lead Site, you can complete steps 2 &amp; 3.</li> </ul>			
STEP	EP       ADD PARTICIPATING SITES TO THE STUDY IN IREX			
2	<ul> <li>A. Click Add Participating Sites in your Checklist, this will open your Sites tab.</li> <li>B. Search and add site(s) by the institutions' name (avoid abbreviations, e.g. "VUMC") or by Federalwide Assurance (FWA) # (numeric characters only) or select a consortium of sites.</li> <li>Add Participating Constraints of the sites that match the name/FWA # will appear. Select the site from drop-down list.</li> <li>You can add sites that do not appear in the drop-down list by typing the site name/FWA # and pressing enter on your keyboard. An IREx admin will create the site in IREx and notify you when you can add contacts.</li> <li>C. Enter the PI and Study Team Member contact information, if known at the time. If not, Save the site and return later to add this information.</li> </ul>			
STEP	REQUEST REQUIRED AGREEMENTS (IF AVAILABLE)			
3	<ul> <li>A. On the Status Summary tab, any institution that is missing agreements will have an orange number of Agreements Complete button with a drop-down list of agreement(s) required for the study.</li> <li>B. Click the purple Request Agreement(s) button to send an email notification to the site.</li> </ul>			

STEP	UPLOAD INITIA	L SIRB APPROVAL FOR T	HE LEAD SITE/OVERALL STUDY & PUBLISH
4	Mellon Univ. Med Ctr Checklist	A. Click Upload Overall Study	Approval in your Checklist. (For more detailed
	Upload Overall	instructions, please vie	w <u>this Quick Guide</u> .)
	Study Approval	B. Change the Status to Appr	oved and indicate the reviewing type & cycle. All
	Publish Approval	required fields and docum	nents will be highlighted in red.
	Add Participating Sites	C. Enter the dates for when i	t was submitted, approved, review, and expires.
	View Site Progress on	D. Upload your documents.	
	Status Summary	Remember to click Ac	cept Draft if the original protocol uploaded to IREx was
	Upload Relying Site     Approval	approved or click Rep	lace Draft if it was modified during the review, in which
		case be sure to chang	e the Uploaded Documents
		version date BEFORE	Review cannot be approved while documents are still in draft.
		uploading the new file	D. Date
		<ul> <li>Replace or accept oth</li> </ul>	Type Document Approved  Protocol [1,5/4/2023] @ PROTOCOL_v1.docx [DRAFT Approved]  Caracter Death Approved Death Approved Protocol v1.docx [DRAFT Approved]
		draft documents, as n	eeded.
	E. Publish Approv	val to make the approved	global
	documents visil	ole to the participating sites on	ce they have study access. Check the box at the bottom of
	the Review & S	ubmit page and	· · · · · · · · · · · · · · · · · · ·
	click <b>Save.</b> Lo	eave the box Publish Lead Site	e / Overall study approval documents. If applicable, sites are not notified and cannot view these documents until ral is uploaded and saved.
	unselected and	click Save if you	
	want to retu	rn to Publish	Cancel Save
	Approval later.		
Step	<b>OPTIONAL: UP</b>	LOAD ADDITIONAL NON	-SIRB REVIEWED DOCUMENTS TO THE
5	ONBOARDING	ТАВ	
	If you have a site sp	ecific consent template, part 2	🖆 Onboarding 🖉 Approvals 🖽 Status Summary 🏛 Sites 🗳 Contacts Eot Study Inform
	consent template,	or other document(s) to help	Onboarding
	facilitate site's loca	submission process, add those	
	documents to the C	)nboarding tab. Here, sites will	be sIRB Instructions
	able to access those	a documents, along with their s	
	moves forward voi	have the ability to Archive	Additional Documents +Add Document
	outdated documen	ts, and continue to add docume	If applicable, relying sites can use the additional documents below to facilitate their local submission process. Please contact the Reviewing IRB Contact or Study Manager with any questions.
	sites should have a	ccess to that do not go through	Arragementinetrations dory
	sIRB review.		2-Part Consent Information docx
STED	NOTIEV 8. CDA		
	A Click Grant Site	Access on your Checklist this	will open your <b>Status Summary</b> tab
6	B Click the Notif	& Grant Access button to aler	t sites of their access to the study in IRFx. This sends an
	email to the H	RPP and study team to prompt	them to connect around their local reliance process, gives
	them study acc	cess, and includes single IRB ins	tructions for the study. <u>The study team can use the Study</u>
	Link in the ema	<u>ail to log into IREx and downloa</u>	d the lead site sIRB approval documents for their local
	submission (if	applicable).	🗈 Onboarding 🖉 Approvals 🖽 Status Summary 🏦 Siles 👙 Contacts Eat Study into 🕶
	Only sites	:hat have joined IREx Checklist	Status Summary
	can be not	Add Par	Export Data 🗸
	<ul> <li>You can no times dong</li> </ul>	or tiry sites at different	Site Agreements O Considerations Status
	are being o	nuing on when they status s	e Progress on ummary Carnegie University 2/2 Agreements Complete • Started 0/3 Surveys Complete • Not Approved
	studv.	Approva	Relying Site Evan University  I 1/2 Agreements Complete - Medical Center
	,		Melion University 2/2 Agreements Complete - Stotity & Grant Access
			Medical Center

STEP	TRACK SITES' READINESS FOR SIRB REVIEW				
7	Use your <b>Status Summary</b> tab to tr	e your <b>Status Summary</b> tab to track your sites' progress.			
	🖨 Onboarding 🖉 Approvals	🖽 Status Summary 🏛 Sites 🔹 Conta	cts Edit Study Info -		
	Status Summary				
			Manage Agreements Export Data -		
	Q Search:				
	Site	Agreements Reliance Decision 2	Local Considerations     Approval Status		
	Anderson Medical Center	I / 3 Agreements Complete ▼ Notify & Grant Access			
	Central Ohio Medical Center	3 / 3 Agreements Complete      ■ Notify & Grant Access			
	Faraday Institute of Research, Science and Technology	3 / 3 Agreements Complete - Contacted 4/13/2023			
	Mellon University Medical Center	3 / 3 Agreements Complete - Completed 4/21/2023	3 / 3 Surveys Complete - Not Approved		
	Middle-earth College of Agriculture	3 / 3 Agreements Complete - Started 4/21/2023	1 / 3 Surveys Complete - Not Approved		
			✓ Institutional Profile Confirmed: 4/21/2023		
			× HRP Survey		
		© COPYRIGHT 2023. VANDERBILT UNIVERSITY MEDICAL C	X PI Survey		
	A Has the site signed all the rea	wired agreements?	Email study personnel		
	<ul> <li>SMART IRB Agreement. IA</li> </ul>	A or MOU	Dullara Dailain Land		
	<ul> <li>Indemnification (if application)</li> </ul>	able)			
	IREx Access		Confirmation must accept SSRP		
	B. Has the site's HRPP indicated	reliance?	Add PI Info Required PI information is not		
	• See Reliance Decision Leg	end – Gray is Completed	yet entered		
	C. Are local considerations com	plete?	Access joined IREx so cannot be granted		
	<ul> <li>Institutional Profile: Comp</li> </ul>	pleted by the HRPP; includes insti	tution-level		
	information.		Notify & Grant         Site has IREx           Access         access and can be		
	HRP Survey: Completed by	y the HRPP; includes applicable lo	Cal notified of study access		
	PI Survey: Completed by t	iy. .he Pl or Study Team Member: in:	Contacted Site has access; click to re-send		
	information about the cor	nduct of the study and an upload	of the locally		
	reviewed consent docume	ent(s). The PI must attest to the s	urvey, as well as		
	any edits made by a Study	/ Team Member or the HRPP.	Completed HRPP has ceded		
	<u>CCP Summary of Results:</u>	Uploaded by PI or Study Team Mo	ember (Pl		
	attestation required). This	s upload is only available for Exce	ption from		
	Informed Consent (EFIC) S	ensure the study team has submi	tted to their local IRB. If so, ask the study		
	team to follow up with their IREx I	HRPP Liaison (found here) regard	ing steps in IREx or other requirements.		
		, 0			

# **STEP PRE-SCREEN AND EXPORT LOCAL CONSIDERATIONS** (IF APPLICABLE)

- You will receive an email when sites complete local considerations. Go to the **Status Summary** tab to review. A. **Pre-screen** the surveys for completion by clicking the 3/3 Surveys Complete dropdown to view the
  - survey list, then click on the HRP Survey and PI Survey.

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- B. Verify consent forms are uploaded to the PI Survey, if applicable, and that they are correct. If changes or clarifications are needed, the PI and Study Team Member (or HRPP Liaison) at the site can edit the PI Survey. Only the HRPP can edit the HRP survey.
- C. Click Export Data and select Export Local Considerations to download a zip file of sites' completed local considerations. Select the site(s) you need and save their files.
- D. Submit the site's files to the sIRB for review. Contact the sIRB about submisson requirements.

🖿 Onboarding 🖉 Approvals	⊞ Status Summary	1 Sites 😂 Contacts	Edit Study Info -
Status Summary			
Site	Agreements	Reliance Decision 😯	Manage Agreements     Export Data ▼       Local Considerations <ul> <li>Approval Status</li> <li></li></ul>
Anderson Medical Center		Notify & Grant Access	
Central Ohio Medical Center	3 / 3 Agreements Complete -	Notify & Grant Access	
Faraday Institute of Research, Science and Technology	3 / 3 Agreements Complete •	Contacted 4/13/2023	
Mellon University Medical Center	3 / 3 Agreements Complete ▼	Completed 4/21/2023	3 / 3 Surveys Complete - Not Approved
Middle-earth College of Agriculture	● 3 / 3 Agreements Complete ▼	Started 4/21/2023	Institutional Profile     Confirmed: 4/21/2023
University of the Bay	Ø 3 / 3 Agreements Complete ▼	Completed 5/16/2023	HRP Survey Completed: 4/21/2023     Click to     prescreen     each survey
			Completed: 4/21/2023 PI Attested: 4/21/2023
			Email study personnel

**IREx Tip (EFIC Studies)**: Exception from Informed Consent (EFIC) studies have 4 Local Considerations surveys, rather than 3. The fourth survey is the CCP Summary of Results, which does not get uploaded by the Relying Site Study Team until the Community Consultation Plan has been implemented. Follow the steps below for EFIC studies.

#### 1. Documenting CCP Acceptance

- You will receive an email when sites complete their Institutional Profile, HRP Survey, and PI Survey (which contains an upload of the CCP for sIRB review. Follow steps A – D above to submit to the sIRB as you would for a non-EFIC study.
- Document the sIRB's CCP acceptance by clicking **Awaiting CCP Acceptance** in the **Approval Status** column and inputting the dates of submission, review, and approval. (The accepted CCP may be uploaded; this is optional.)
- 2. Submitting The CCP Summary of Results for sIRB Approval
  - Once the study team has implemented their CPP and is ready to submit their CCP Summary of Results, they will do so via IREx, and you will receive another IREx notification. Return to the Status Summary tab and follow steps A – D above to submit the CCP Summary of Results to the sIRB for their review.
  - Once the CCP Summary of Results is approved and you are ready to document the Relying Site's initial approval, continue to Step 9.

9	A. Click Upload Relying Site Approval on your Checklist				
	or click the Not Approved status for the site you wish		Vanderbilt Univ		
		to upload approval for on the <b>Status Summary</b> tab.		Status	Review Type
		(For more detailed instructions, please view <u>this Quick</u> <u>Guide</u> .)		When you save this approval, an email will be sent to the relying site's HRPP and study teams. If you are not ready to notify the site of their approval, change	Initial Study: Full Board
	В.	Select the site from the list of sites on the left panel.		the Status to pending.	
	C. Change the Status to 'approved' and required items will turn red.		Is Site Enrolling? System Constraints of No Date Submitted mmiddyyyy A Required	Add pre-review exchanges with PI	
	D.	Indicate the <b>Review Type</b> (Full Board or Expedited).		Date Pre-Reviewed	
	Ε.	Is Site Enrolling? Defaults to Yes, change to No if the		Date Reviewed	Add post-review exchanges with PI
		site will not be enrolling participants and does not		Required     Add another Review Date	
	need a consent form.			Date Approved	
	F.	Enter the Date Submitted, Reviewed, and Approved		A Required	
	G.	Upload the site's IRB Approval Documentation,			
		Consents & Assents (or waive), and other site-specific		IRB Approval Documentation	Date Approved
		IRB approved documents.		or drag it here.	
	Н.	Click Save.		Consents & Assents	
	The	e site HRPP and study team are notified by email when		or drag it here.	

### **ADDITIONAL RESOURCES**

- A. Uploading other approvals (see quick guides below)
  - <u>Continuing Review</u>
  - <u>Study-wide Amendments</u>
  - <u>Site Amendments</u>
- B. Site closures Closing a site ensures that only active sites retain access to ongoing studies.
  - Site Closure Quick Guide
- C. **Study closures -** Closing a study ensures all sites are aware that the study ended but retains a record of the reliance and a history of sIRB site approvals.
  - Study Closure Quick Guide